result in the DETERMINE® Syphilis test at follow-up. False positive tests with DETERMINE® Syphilis test were defined as being non-confirmed by combined cardiolipin and specific treponemal positive tests at baseline and negativity in the follow-up period.

Results Of all positive results with the DETERMINE® Syphilis test 14.0% were shown to be true positive results by fulfilling one or more of the aforementioned criteria, compared to combined conventional tests. Compared to the use of single cardiolipin tests, the DETERMINE® test detected 27.1% more cases. False positive tests with DETERMINE Syphilis TP test occurred 0.26% of those patients tested.

Conclusions The DETERMINE® syphilis test is superior to treponemal and cardiolipin tests alone or in combination in the detection of syphilis in Primary Care.

P2.072 SEEK AND YOU SHALL FIND - VALUE OF EXTRAGENITAL CHLAMYDIA AND GONORRHOEA TMA TESTING IN A COHORT OF MSM

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Background TMA (Aptima Combo II) is unlicensed for the detection of chlamydia and gonorrhoea at extragenital sites but is increasingly used to screen MSM reporting receptive oral or anal intercourse as data accumulates to support its performance. We reviewed its value in screening our MSM cohort.

Methods The TMA and culture results of MSM receiving extragenital screening between 01/01/12 and 30/06/12 were retrospectively reviewed.

Results 565 MSM were screened (1042 extra-genital samples); 95 tested positive for at least one infection at one site.

111 positive TMAs were extragenital (detection rate 10.7%) amongst 87 patients. 68 patients had isolated extragenital infection.

41 MSM (8.5%) had rectal chlamydia, only 5 of whom had genital chlamydia; 7 were confirmed LGV.

8 (1.4%) MSM had pharyngeal chlamydia. 4 had concurrent rectal infection; none had urethral infection.

Urethral chlamydia was detected in 16 MSM (2.8%).

27 (5.6%) MSM had rectal gonorrhoea via TMA; 11 were positive on culture.

35 (6.2%) MSM had pharyngeal gonorrhoea via TMA; 8 were positive on culture.

12 (2.1%) MSM had urethral gonorrhoea; 11 were positive on culture.

Conclusion 15.4% MSM attending for tests had extragenital infection. 71.6% testing positive had isolated extragenital infection. Without extragenital TMA tests 49 chlamydia infections would have been missed or suboptimally treated, including 7 LGV.

25/52 cases of gonorrhoea would have remained undiagnosed had screening been by 3 site culture and urethral TMA.

Undiagnosed extragenital infection has implications regarding onward transmission of that STI and may result in missed/suboptimal treatment and partner notification. Failure to screen effectively may provide false reassurance and reinforce popular myths that the pharynx is not vulnerable to infection. This data supports our current practise of TMA testing at extragenital sites.

P2.073 EXTRAGENITAL SCREENING IN WOMEN - IS TMA VALUE FOR MONEY?

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Background Transcription mediated amplification (TMA, Aptima Combo II) is currently unlicensed for the detection of chlamydia and gonorrhoea at extragenital sites. Accumulating evidence suggests TMA has high sensitivity and specificity for pharyngeal and rectal infection. We have offered pharyngeal and rectal TMAs to all patients presenting since April 2009 reporting receptive oral or anal intercourse.

Methods The TMA and culture results of heterosexual women receiving extragenital screening between 01/01/12 and 30/06/12 were retrospectively reviewed.

Results 1315 women were screened (1520 extra-genital samples), 79 tested positive for at least one infection at one site. 62 (4.7%) patients had genital chlamydia. 9 (0.7%) patients had genital gonorrhoea.

33 positive results were extragenital (detection rate 2.17%) with 10 patients having isolated extragenital infection.

Rectal chlamydia detection rate was 3.8%. Of the 8 patients with rectal chlamydia, 7 had co-existing genital infection.

14/1309 (1.1%) patients had pharyngeal chlamydia, 5 had isolated pharyngeal infection.

6/211 (2.8%) patients had rectal gonorrhoea, 1 had isolated rectal infection.

5/1309 (0.4%) patients had pharyngeal gonorrhoea, 3 had isolated pharyngeal infection.

There were no positive extragenital gonorrhoea cultures and no cases of extragenital dual infection.

Conclusion Detection rates for extragenital chlamydia (both sites) and rectal gonorrhoea exceeded that of genital gonorrhoea.

Without extragenital screening we would have failed to treat 10 women with isolated pharyngeal or rectal infection, i.e. 12.7% of all women testing positive.

Regarding the 8 women with rectal chlamydia, 7 could have been suboptimally treated with azithromycin and one would have been missed.

This has implications for onward transmission, enhanced transmission of other STIs, and missed opportunities for partner notification.

Failure to screen women extragenitally may reinforce the misconception that these sites are not as significant in STI transmission and encourage risk taking behaviour.

P2.074 COMPARISON OF SPECIMEN TYPE FOR THE DIAGNOSIS OF *TRICHOMONAS VAGINALIS* (TV) USING THE VIPER™ SYSTEM IS EXTRACTED MODE

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Background TV is the most common curable STI worldwide and is associated with adverse consequences including preterm birth and acquisition/transmission of HIV. Yet, until recently, testing options for this infection were limited and had suboptimal sensitivity. Recently, nucleic acid amplification test systems (NAATS) for diagnosis of TV have been developed. Various types of specimens were studied in this process. We now report on the agreement of these specimen types for the diagnosis of TV using this NAATS assay.

Methods Eight centres participated in this study. Specimens were collected from subjects presenting with symptoms of trichomoniasis or for routine visits. Specimens were collected in the following order: (1) first void urine, (2) patient-collected vaginal swab, (3) three clinician-collected vaginal swabs, (4) endocervical swab. Urine was aliquotted into a Viper neat and UPT tube for BD ProbeTec™ *Trichomonas vaginalis* (TV) Q^x Amplified DNA Assay (TVQ) testing. The three clinician-collected vaginal swabs were used for wet mount, culture, and comparator testing. Sensitivity and specificity for the specimen

types were calculated by comparing results to the patient infected status (PIS) algorithm of wet mount and TV culture.

Results Results from 838 participants were available for evaluation. The overall prevalence of TV in this population was 120/838 (14.3%). Using the self-collected vaginal swab as the reference comparator, there was excellent agreement between vaginal swabs, neat and UPT urine, and endocervical swabs (kappa 0.93–0.95). Of these specimen types, endocervical had the lowest yield but still had excellent agreement with vaginal specimens.

Conclusions Vaginal, urine, and endocervical samples showed excellent agreement for diagnosis of TV and are all acceptable specimens for use with the BD Viper™ System in extracted mode. The development of NAATS testing for TV, especially with the potential use of self-collected vaginal swab and urine specimens should greatly facilitate screening for this common STI.

P2.075 EVALUATION OF FEMALE URINE AND VAGINAL SWABS USING THE BD PROBETEC™ *TRICHOMONAS VAGINALIS* Q^x AMPLIFIED DNA ASSAY ON THE BD VIPER™ SYSTEM IN EXTRACTED MODE AND A CLEARED NAAT TV ASSAY AS COMPARED TO PIS

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Background *Trichomonas vaginalis* (TV) is a sexually transmitted organism associated with vaginitis, cervicitis, urethritis, low birth weight, preterm delivery, pelvic inflammatory disease and HIV transmission and acquisition. Nucleic acid amplification testing improves the sensitivity for detection of pathogens. The performance of the BD ProbeTec™ TV Q^x (TVQ) Amplified DNA Assay and the Gen-Probe Aptima TV assay were compared to patient infected status (PIS) established by the InPouch TV culture and wet mount for the detection of trichomonas in women.

Methods Participants with symptoms of trichomonas or presenting for routine visit were enrolled from seven geographically diverse centres. First void urine, a patient collected vaginal swab, and three clinician-collected vaginal swabs were obtained from each participant. Urine was aliquoted into BD neat and UPT tubes as well as an Aptima UTT tube. The first two clinician-collected vaginal swabs were randomised for wet mount and InPouch TV culture. The third was used for the Aptima TV assay.

Results There were a total of 1034 compliant participants with evaluable PIS. Specimen and instrument level exclusions resulted in 830 compliant vaginal result sets and 733 neat, UPT and UTT urine result sets for evaluation. For vaginal specimens, the sensitivity (specificity) of the TVQ Assay and the Aptima TV Assay compared to PIS were 98.3% (99%) and 100% (98.3%), respectively. For BD neat and UPT urine specimens, the sensitivity (specificity) of the TVQ Assay compared to PIS were 95.5% (98.7%) and 94.6% (98.6%). For the Aptima UTT urine specimen, the sensitivity and specificity of the Aptima TV Assay compared to PIS were 97.3% and 98.7%.

Conclusion The BD ProbeTec™ *Trichomonas vaginalis* Q^x Amplified DNA Assay on the BD Viper™ System in extracted mode demonstrated excellent performance characteristics that were comparable to the only commercially available nucleic acid amplification assay for the detection of *Trichomonas vaginalis.*

P2.076 DEVELOPMENT OF A MOLECULAR BEACON-MEDIATED DIAGNOSTIC PROBE ASSAYS FOR THE DETECTION OF TRICHOMONAS VAGINALIS IN DRY SWABS SPECIMENS OF SYMPTOMATIC WOMEN

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Introduction Trichomonas vaginalis (TV) is a protozoan parasite that infects the genitourinary tract of 250 million individuals annually, leading to trichomoniasis. The Infection is associated with preterm delivery, low foetus birth weight and increased susceptibility to other STDs as well as increased HIV acquisition. Infection with Trichomonas is globally underestimated because of ineffective screening protocols and under equipped pathological laboratories especially in developing countries. As a consequence, trichomoniasis is associated with poor reproductive health, with numerous clinical squeal and complications. In developing countries like India, due to forbidden cost of commercial kits, syndromic management is preffered. Hence, a cost effective and quick diagnostic assay is urgently required. The present study is an attempt to develop an inexpensive, specific and sensitive quantitative assay for Trichomonas vaginalis.

Methods Specimens were retrieved consecutively from patients with vaginal complaints. In-house primers and molecular TV beacon (Tv-B) were designed to detect the presence of unique regions in the genome of Trichomonas in clinical isolates. The sensitivity and specificity of the inhouse primers were evaluated against published primers and the method was validated against qPCR based commercial kit using DNA isolated from 802 dry clinical swabs.

Results In-house designed PCR based assay for detection of trichomonas was highly sensitive as could detect as low as 10fg of genomic DNA (3–5 pathogens). Using molecular beacon, Tv-B, 83 women (10.3%) tested positive for trichomonas out of 802 women (age 15 yrs –55 yrs). The assay was extremely specific and sensitive (99.25% and 94.64% respectively). The PPV was found to be 94% and NPV was 99%. The assay could be used for quantification of load of infection.

Conclusion The results demonstrated that in housed developed test for TV is highly specific, sensitive, pocket and user friendly.

P2.077 USE OF THE OSOM® TRICHOMONAS RAPID TEST IN AN EMERGENCY ROOM SETTING

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Background The availability of sensitive point-of-care tests for *Trichomonas vaginalis* (TV) in emergency rooms (ER) is important to facilitate immediate diagnosis and treatment. We evaluated the use of the OSOM® Trichomonas Rapid Test, an FDA-approved immunochromatographic capillary flow assay, among female patients in an ER located in the southeastern United States.

Methods The University of North Carolina Hospitals located in Chapel Hill, North Carolina, US replaced wet mount microscopy (WM) for vaginal TV detection with the OSOM® Trichomonas Rapid Test (Genzyme Corporation, US) in October 2011. We analysed 10 months of data for women evaluated in the ER with the rapid test, and compared the positivity rate with a similar 10-month period determined by WM. We assessed characteristics of women identified with trichomoniasis using the rapid test, and the proportion who received appropriate therapy.